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- (71) Applicant (for all designated States except US): GS DE-VELOPMENT AB [SE/SE]; Jägershillsgatan 15, S-213 75 Malmö (SE).

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(72) Inventors; and

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- (75) Inventors/Applicants (for VS only): HÅKANSSON, Håkan (SE/SE); Astrakanvägen 6, S-224 56 Lund (SE). LUNDBORG, Göran (SE/SE); Önneslöv 16, Björnstorp, S-240 13 Genarp (SE). STÅHL WERNERSSON, EVA (SE/SE): SØRD FERDERIOR 15, AS - 222 56 Lund (SE).
- Declarations under Rule 4.17:
- S-240 13 Genarp (SE). STÁHL WERNERSSON, Eva [SE/SE]; Södra Esplanaden 15 A, S-223 54 Lund (SE).
 (74) Agents: BENGTSSON, Peggy et al.; Albihns AB. PO
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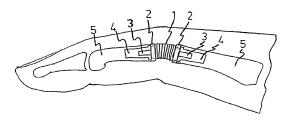
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(54) Title: PROSTHETIC DEVICE FOR JOINTS

Box 4289, S-203 14 Malmö (SE).



(57) Abstract: A prosthetic device for joints for implantation in humans and animals, the device comprising a joint body (1) including two or more substantially helical springs arranged hetween two fixing elements which are adapted to be connected to adjoint body bone parts (5), each fixing element comprising a base plate connected to the joint body, and a fixing member (3) projecting from the base plate (2), wherein the fixing members (3) project away from each other at an angle in the range of 20 to 30 degrees when the springs (1) are in their resting position.

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Prosthetic device for joints

Field of invention

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The present invention relates to a prosthetic device for joints for implantation 5 in humans and animals, the device comprising a joint body arranged between two fixing elements which are adapted to be connected to adjoining bone parts.

Background of the Invention

Several diseases cause destruction of joints, resulting in chronic pain and 10 impaired movability. The problem is most pronounced in patients who suffer from chronic rheumatoid arthritis, but is also pronounced in, for instance, osteoarthritis (wear of cartilage) and in articular cartilage injuries after fractures and bacterial infections. In many of these cases the diseased and injured joint is replaced by an artificial joint structure.

However, experience has shown that too great an ambition to completely imitate the function of a normal joint in many cases results in failure. The artificial joint will easily be too complicated. For a rheumatic who has no joint function at all in, for instance, in hands, it is not necessary to aim at regaining a fully normal joint function via a prosthetic operation. The aim should instead be to obtain a painless 20 joint with stability and a certain amount of movability, which makes the hand usable. Thus, the aim of the join structure must always be related to the patient's needs.

The main difficulties when constructing artificial joints in e.g. the hand have been (1) to provide an artificial joint with satisfactory properties and (2) to fix the 25 artificial joint to adjoining bones in a satisfactory manner.

WO 97/26846 discloses a prosthetic device comprising a joint body which includes one or more substantially helical spring means arranged between two fixing elements which are adapted to be connected to adjoining bone parts. This prosthetic device obviates many of the drawbacks that are associated with other 30 known artificial prosthetic devices for joints that are available today. However, undesired tissue ingrowth in this system can occur between the windings of the spring, and this may cause an adverse tissue reaction which can lead to inflammation and stiffening of the joint. Furthermore, the springs of this system is always susceptible to wear and friction, and the endurance of the springs are 35 essential for the function of the prosthetic device.

Summary of the Invention

The general object of the present invention is to provide a prosthetic device for joints that obviates the drawbacks that are associated with artificial prosthetic

devices for joints that are available today. More particularly, the object of the present invention is to improve the artificial joint disclosed in the international Patent Application WO 97/26846.

One factor of importance is the endurance of the springs of the prosthetic

5 device. The spring will be subject to friction and fatigue caused by movements of
the joint, and eventually wear out. Durability and a long functional life time of the
spring is of great importance.

Another factor of concern is the adverse tissue reactions that may be caused by undesired tissue ingrowth between the windings of the spring, which can lead to 10 inflammation and stiffening of the joint.

In order to fulfill the objects is provided a prosthetic device for joints useable for implantation in humans and animals, the device comprising a joint body including two or more substantially helical springs arranged between two fixing elements which are adapted to be connected to adjoining bone parts, each fixing element comprising a base plate connected to the joint body, and a fixing member projecting from the base plate, where that the fixing members project away from each other at an angle in the range of 20 to 30 degrees when the springs are in their resting position. In alternate embodiments the fixing membersmay project away from each other at an angle in the range of 23 to 27 degrees or in the range of 24 to 26 degrees.

Each of the fixing members projects from the respective base plate at an angle of 10 to 15 degrees in relation to the longitudinal direction of the joint body. In alternate embodiments they project at an angle of 11,5 to 13,5 degrees in relation to the longitudinal direction of the joint body or at an angle of 12 to 13 degrees in 25 relation to the longitudinal direction of the joint body.

The prosthetic device as above where each spring has tight windings, which are closed in its resting position and where each spring is a cylindrical, helical tension spring.

The prosthetic device is preferably intended for reconstruction of the
30 metacarpophalangeal joints (MCP), the proximal interphalangeal joints (PIP) or the
distal interphalangeal joints (DIP) in humans.

Description of the Drawings

The present invention will be described in more detail below, with the aid of 35 a number of preferred embodiments and with reference to the accompanying drawings, of which:

Fig. 1 illustrates a finger having one of its joint replaced by a prosthetic device according to the present invention.

Fig. 2 illustrate, in a side view, a prosthetic device of the present invention with a 25 degree preflex angle.

Fig. 3 is a photo illustrating the encapsulation of a closely wound spring of the present invention.

Fig. 4 illustrates the endurance in bending fatigue tests for springs with different wire diameter.

Fig. 5 illustrates the endurance in bending fatigue tests for springs having different spring coil diameters.

Fig. 6 illustrates the endurance in bending fatigue tests for springs having 10 different spring coil lengths.

Fig. 7 illustrates the endurance in bending fatigue tests for springs with different wire material and wire diameter.

Detailed description of the embodiments

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By the expression "substantially helical" springs is meant a helical spring having at least one winding and a structure where minor deviations from the helical shape may occur, without affecting the properties of the spring in an undesired manner.

By the expression "longitudinal direction of the joint body", which is below 20 used throughout, is meant the axial direction in which the joint and its adjoining bone parts extend in stretched condition.

Fig. 1 is a side view of a preferred embodiment of a prosthetic device for intermediate finger joint having a joint body 1 of two parallel helical cylindrical springs 1 arranged in a plane perpendicular to the plane of bending of the joint body
1 and the finger. These two springs 1 are, at each end, via a base plate 2 and a fixing member 3 fixed to anchoring means 4 in adjoining bone parts 5.

During their course of research in the field of prosthetic joint implants, the inventors have found that the angel of joint implant of the present invention should be in a specific range to be optimal. The fixing members (3) of the present invention are arranged to project away from each other at an angle in the range of 20 to 30 degrees, forming a preflex angle. Fig. 2 illustrates the prosthetic device of the present invention were the fixing members (3) of the present invention project away from each other at an angle in the range of 25 degrees. After surgery the natural resting position of the hand in the metacarpophalangeal joint (MCP) and the proximal interphalangeal joint (PIP) is about 20 to 30 degrees in relation to the longitudinal direction of the joint. Hence, the springs of the prosthetic device of the present invention will when implanted in the MCP or PIP joints be closed and in an unstrained resting position when the body joint is in its natural resting position. This

will lead to the positive effect of a faster formation of an encapsulation around the springs, since a closed spring facilitate the encapsulation process.

Fig. 3 illustrates the encapsulation of a spring of an artificial joint according to an embodiment of the present invention. According to this invention a closely 5 wound tension spring is preferably used. Such a tight cylindrical structure does not hamper, after implantation in a biological tissue, the fast formation of a thin outer tissue membrane around the helical spring, i.e. some kind of physiological encapsulation. This encapsulation reduces the risk for adverse tissue reaction.

When implanted in the MCP or PIP joints, the bending movement that the 10 springs will be subjected to extends from a full extension of the fingers, i.e. a flexion of 0 degrees, to a full downwards flexion, i.e. 90 degrees. With the 20 to 30 degrees preflex angle of the prosthetic device of the present invention, the full flexion (90 degrees) of the joint will only bend the springs 60-70 degrees, and a fullextension of the joint will bend the springs 20-30 degrees in the opposite 15 direction. Thus, the maximum bending angle of the springs, is reduced and thereby the load and wear on the springs, which result in an increased endurance and a reduced risk of spring fracture.

According to the present invention, use is made of two or more springs as supporting joint body 1 in the prosthetic device. Studies have shown that optimum 20 stability is usually obtained when using a plurality of springs.

The prosthetic device for joints according to the present invention, i.e. the springs, the base plates 2 and the fixing members 3, can be made of any biocompatible materials that are suitable and approved for implantation, e.g. titanium or stainless steel.

2.5

The choice of material of the wires of the springs is of great importance. For many implantable devices titanium is a preferred material. However, in this application the fatigue resistance of a titanium wire was not considered acceptable. Therefore, in a preferred embodiment of the present invention, the material of the wire found to be suitable is MP 35N (Fort Wayne Metals, IN), a material which 30 among other things is used in pacemaker electrodes. The manufacturing of this wire material includes a drawing process in which the properties of the wire can be adjusted within certain limits. In one embodiment of the invention the MP 35N wire material has a strength of 2170 MPa.

The purpose of the design of the joint body 1 according to the invention is in 35 the first place to distribute, over a long distance, the deformation in the joint body induced by bending movements although the movement per se must be contained within the short distance that corresponds to the normal extent of the joint. As a result, the risk of the material being damaged is reduced. A large movement in the artificial joint is "geared down" to a large number of small movements over the

entire length of the helical springs. For instance, a helical spring having a diameter of 5 mm and a length of 10 mm can easily contain 300 mm wound material and all the same offer resilience, stability and flexibility suitable for the purpose. By the fact that the springs per se constitute the supporting, flexible and stabilising basic 5 structure of the joint body 1, the need of a further deformable supporting joint body, e.g. of polymer material, is eliminated,

Each spring can be attached to the base plate 2 in any conventional manner that affords the joint body 1 sufficient stability and durability. The springs can be attached to the plate inside an opening of the base plate 2. This opening which 10 creates an aperture can be made conical in order not to wear on the springs. The springs can be attached to the base plate 2 by means of a weld seam, by gluing or by the ends of the windings of the springs being "screwed" over the base plate 2 and locked in position, for instance by means of a groove or a recess in the plate. Laser welding has proven to be a good method to attach a springs to a base plate. These 15 methods of attachment and other similar methods can be used separately or in combination.

The base plates 2 are adapted to be connected, via the fixing members 3, to fixed anchoring means 4 inserted in adjoining bone parts 5 on each side of the prosthetic device for joints. Several conventional, suitable methods for attachment 20 are available. An established method means, as mentioned above, that the fixing members 3 in the form of shafts, which protrude from the base plates 2, are inserted in longitudinal channels in the longitudinal direction of the anchoring means 4. The anchoring means 4 can be made of ceramic material, titanium or some other material having suitable biological and mechanical properties.

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The helical springs that are to be used as joint body 1, is preferably tension springs. A tension spring is closely wound and affords good lateral stability in the system and resistance when tensioned. Such a tight cylindrical structure induces, after implantation in a biological tissue, the formation of a thin outer tissue membrane around the helical spring, i.e. some kind of physiological encapsulation. 30 From figure 3 can be seen that the wire of a spring 310 forms a completely closed structure which is encapsulated in a thin membrane 320. This membrane has a natural and healthy look. If it had been inflammatory it had been opaque, swollen and provided with a different kind of vascular genesis. In the picture the blood vessels are healthy and of natural size and quality. This encapsulation reduces the 35 risk for adverse tissue reaction. Tension springs do not allow any further compression in the system, but yield satisfactory stability and resilience in case of lateral wobbling.

The prosthetic device for joints according to the present invention can be of different embodiments, depending on the position in the body, where they are to be

implanted and how they are intended to function. Thus, a number of similar or different, substantially parallel springs can be used in combination, one or more of the springs differing from the others, and/or each varying in itself in respect of winding cross-section, pitch, pitch angle and/or wire cross-section. One or more 5 springs can also be substantially concentrically arranged inside one or more bigger springs, or be inserted into each other according to a principle similar to that of e.g. a DNA molecule. By the expressions "substantially parallel" and "substantially concentric" are meant that a small deviation in the longitudinal direction between different springs is comprised in the scope of protection of the invention. The 10 springs are in their longitudinal directions preferably cylindrical, but can also be convex or concave. Below follows a detailed description of some various embodiments.

Joint Body with a Varying Number of Springs

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Two or more parallel springs arranged in a plane which is perpendicular to the plane of bending of the joint body 1 give good lateral stability and retained satisfactory movability in one plane (see the embodiment in Fig. 2). When reconstructing a joint, both bending and stretching are thus made possible, as well as a certain amount of restricted lateral deviation. Such a joint body 1 is particularly 20 suitable for reconstruction of the knuckle joints (MPC joints) and the intermediate joints of the fingers (PIP joints).

Joint Body with a Varying Number of Springs and a Varying Positioning thereof

By varying the positions of the springs on each base plate 2, the mechanical 25 properties of the prosthetic device for joints can be modified and controlled. For example, one or more springs can be located inside one or more bigger springs or in other suitable positions. More than two springs in the joint body cause increased reliability if one of the springs should break.

30 Joint Body having a Varying Section of the Spring Wire

The mechanical and biological properties of the springs can be varied by varying the section of the wire. Its cross-section can be e.g. round, oval, transverse or inclined in different planes.

35 Joint Body with Springs of Varying Length

The length of the springs can be varied as required. A longer spring will get less stress than a shorter one, but will be less stable than the shorter one. In small joints, for instance in the intermediate and outer joints of the fingers, it is usually advantageous to have very "short" springs. The length of the springs is also

influenced by the desire to cut away as little bone as possible. In one embodiment of the present invention the total length of the joint body, i.e. the distance between the adjoined bones, of the prosthetic device for PIP joints is 6 to 8 mm

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5 Joint Body with Springs having a Varying Winding Diameter

The winding diameter of the springs can, like in conical helical springs, be varied in different ways along the length of the spring. The spring can be, for instance, convex ("egg-shaped") with its greatest diameter in the centre or concave ("hour-glass-shaped") with its smallest diameter in the centre. In this way, the winding of the springs when bent and stretched can be displaced in relation to each other in a manner that is not possible with a common cylindrical spring, which may be desirable in certain applications.

As mentioned above, the base plate 2 in the prosthetic device for joints according to the present invention can be made of any suitable biocompatible material whatever. The design of the base plate 2 is not critical for the present invention, but it may be of any suitable plate shape.

However, that surface of the base plate 2 which is directed to the fixing member 3 can be angled in relation to the longitudinal direction of the joint body 1. Moreover, the surface which is directed to the joint body 1 of a base plate 2 for two springs can be angled, i.e. such that the springs, which are arranged in a plane perpendicular to the plane of bending of the joint body 1, in the resting position in the longitudinal direction of the joint body 1 form arcs curved away from each other. Such a design results in even and smooth lateral stability in the joint body 1. If required, the base plate 2 can also be designed such that more than two springs form arcs in the resting position.

After implantation of a prosthetic device for joints according to the present invention, a thin capsule consisting of a connective tissue membrane automatically forms, as mentioned above, around each spring. This phenomenon is most pronounced when a closely wound tension spring is used. If necessary, each spring can be provided with an artificial outer capsule for the purpose of minimising undesired tissue ingrowth in the system. Such a capsule may consist of a thin membrane of a woven or homogeneously deformable material with suitable biological and mechanical properties. The membrane can be resorbable or not.

The joint body 1 in its entirety can be encapsulated with a surrounding casing having a very close winding and a configuration (e.g. oval or rectangular) which permits enclosure of the joint body 1 itself. When designing such a "capsule", priority is given to the "membrane effect" instead of mechanical strength. When using a closely wound thin wire, a most insignificant widening between the windings of the spring thus takes place, also in case of large movements in the

system. In this fashion, two different types of spring may supplement one another in a favourable way, i.e. a system of interior springs which are responsible for the mechanical properties of the structure, supplemented with an exterior enclosing spring system which is substantially directed to a barrier effect. These two spring systems should be made of a material having suitable biological and mechanical properties.

The forming of an outer biological membrane around one or more springs in the joint body is facilitated by the spring or springs, before implantation, surrounding a tube of a biocompatible, optionally resorbable material, said tube, lowever, not constituting a supporting body for the prosthetic device for joints. In this way, a biological capsule forms automatically around the spring after implantation.

The present invention is particularly applicable to reconstruction of the knuckle joints (MCP joints) and the intermediate and outer joints of the fingers (PIP and DIP joints).

The invention can also be used in the wrist, the thumb base osteoarthrosis as bone replacement for the trapezoid bone or as artificial joint between the first metacarpal bone and the trapezoid bone and/or between the trapezoid and the navicular bone. The invention can also be used as bone replacement for intervertebral discs or individual vertebrae in the spinal column. The present invention is, of course, also applicable to other similar joint and bone systems in the body, also where replacement structures are now rare, but which may be of interest in future, for instance in the joints of the foot.

By selecting a suitable size and configuration of the springs included in the 25 joint body, the contour of the normal articular head can be imitated in a cosmetically advantageous fashion.

The dimensions of the components of the prosthetic device for joints are not restricted, but of course vary depending on the dimensions of the joint or bone part that is to be replaced in the human or animal at issue.

Stress reduction by certain choice of wire diameter

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The bending of the joint causes a twist of the wire of the spring coil 1. A thicker diameter of the wire will lead to a larger stress on the wire as has been verified in tests and simulations see fig. 4. In the figure a diameter of 0.5 mm is compared to other diameters with respect to the incurred stress for a certain angle of bending. In order to prolong the life of the joint different diameterss were tested and a diameter of 0.45 mm was found to have a longer life. This is seen as a lesser stress in the diagrams of fig. 4 and 7.

However, it has also been found that it is not appropriate to reduce the diameter too much, since the stability and the force needed to bend the joint a certain angle will decrease. The findings of the tests and simulations suggests that the diameter of the wire should be not less than 0.40 mm

Stress reduction by certain choice of coil diameter

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The diameter of the spring coil 1 also affects the force needed to bend the joint a certain angle. The spring coil 1 diameter also affects the stability and the length of the wire. This is reflected in figure 5 where a spring coil 1 diameter of 5 mm is compared to other spring coil 1 diameters with respect to the incurred stress for a certain angle of bending. It can be seen that a smaller diameter of the spring coil will make the joint stiffer. The length of the wire becomes shorter, and thereby the stress on the wire becomes higher. However the upper diameter of the spring coil is limited by the space where the joint should be implanted. Threfore, to reduce stress and still have a diameter that fits into available space a diameter of 6 mm is preferred.

Stress reduction by adapting the length of the spring coil

The length of the artificial joint is limited upward by the anatomy of the

20 patient. The longer the artificial joint the more amount of patient bone need to be
cut away to make place for the joint. However, there is always a desire to cut away
as little bone as possible. It was found that a longer wire gets less stress than a
shorter one, as can be seen in fig. 6. Here a spring coil length of 7 mm is compared
to free spring coil length of 6, 9.5 and 12 mm with respect to the induced stress as
25 dependent on bending angle. It can be seen that the material stress in a short spring
coil having length of 6 mm passes the stress threshold already at approximately 45
degrees bending angle. The stress in the material in a spring coil of a length of 9.5
mm passes the stress threshold first at approximately 87 degrees bending angle.

30 <u>Increased stress resistance by choosing appropriate material in the wire of the spring coil</u>

The material of the wire is of great importance. For many implantable devices titanium is preferred. However, in this application, tests have shown that the fatigue of a titanium wire having dimensions suitable for the application, is not acceptable. The inventors have searched for another material and found the wire/material MP35N suitable fot the present application. Materials with similar characteristics regarding biocompatibility and strength would of course also be suitable. As mentioned above, the manufacturing of this material includes a drawing process in which the properties of the wire can be changed within certain limits. A

wire material subjected to a drawing process giving it a strength of 2170 MPa was chosen as the most preferred material for the present application. Fig 7 shows the endurance in bending fatigue tests for springs with different wire material and wire diameter. A wire diameter of 0.45 and an MP 35 material with a strength of 2170 MPa can be bended repeatedly a larger angle without reaching the stress threshold.

Conical hole

Another feature of the mechanical design of the artificial joint is that the hole in which the spring coil is welded into the plate is made conical in order to avoid wear and friction between the spring coil material and the plate.

Example 1

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A prosthetic device adapted for MCP and PIP joints are shown in Fig. 2.

Preferably, it has a length of about 6 to 8 mm and a width of about 4 to 6 mm, each
15 of two helical springs has preferably a length of 4 to 6 mm, a winding diameter of 4
to 6 mm and a wire diameter of 0.4 to 0.55 mm more preferably 0.45 mm. The base
plate 2 has preferably a thickness of 1 to 2 mm. The fixing member 3 has preferably
a diameter of 2 to 3 mm and projects 4 to 6 mm from the base plate.

20 Test Method - Finite Element Method, FEM calculations:

Fig. 4 shows the endurance of springs upon repeated bending as tested with the aid of FEM calculations. Real tests point in the same direction. From this figure it can be seen that a stress threshold for the material, in this case the former mentioned alloy MP 35, is reached for a spring with a wire diameter of 0.7 mm 25 already when the bending angle is 25 degrees.

A corresponding spring with a wire diameter of $0.5~\mathrm{mm}$ reaches the stress threshold when bending approximately $57~\mathrm{degrees}$.

A further corresponding spring with a wire diameter of 0.45 mm will not reach the stress threshold until bending over 70 degrees.

Therefore, a spring with a wire diameter of 0.45 mm will be very well suited for use in an artificial joint according to the present invention with a preflex angle of 25 degrees, since the bending angle of the spring will never exceed 70 degrees, and thus it will endure the repeated bending it is subjected to when being used as replacement for a finger joint.

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CLAIMS

- 1. A prosthetic device for joints for implantation in humans and animals, the device comprising a joint body (1) comprising two or more substantially helical springs arranged between two fixing elements which are adapted to be connected to adjoining bone parts (5), each fixing element comprising a base plate connected to the joint body, and a fixing member (3), projecting from the base plate (2), characterised in that the fixing members (3) project away from each other at an angle in the range of 20 to 30 degrees, when the springs (1) are in their resting position, and where said springs have a wire diameter of 0,40 to 0,55 mm, and where said springs have a spring coil diameter of between 4.0 mm and 6.0 mm.
- The prosthetic device according to claim 1, where the fixing members (3) projects away from each other at an angle in the range of 23 to 27 degrees.
 - The prosthetic device according to claim 1, where the fixing members (3) projects away from each other at an angle in the range of 24 to 26 degrees.
- The prosthetic device according to claim 1, where each of the fixing members (3) projects away from its corresponding base plate (2) at an angle of 10 to 15 degrees in relationship to the longitudinal direction of the joint body (1).
 - 5. The prosthetic device according to claim 1, where each of the fixing members (3) projects away from their corresponding base plate (2) at an angle of 11,5 to 13,5 degrees in relationship to the longitudinal direction of the joint body (1).
 - 6. The prosthetic device according to claim 1, where each one of the fixing members (3) projects out from their corresponding base plate (2) at an angle of 12 to 13 degrees in relationship to the longitudinal direction of the joint body (1).
 - 7. The prosthetic device according to claim 1, where each helical spring has tight windings, which are closed in its resting position.
- The prosthetic device for joints as claimed in any one of the preceding claims, where each spring is a helical tension spring.
 - The prosthetic device for joints in any one of the preceding claims where each spring is cylindrical in its longitudinal direction.
- 45 10. The prosthetic device for joints as claimed in any one of the preceding claims where the prosthetic device is suitable for reconstruction of the

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metacarpophalangeal joints (MCP), the proximal interphalangeal joints (PIP) or the distal interphalangeal joints (DIP).

11. The prosthetic device according to claim 1, where said springs have a spring length of between 6,0 mm and 8,0 mm.

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- 12. The prosthetic device according to any of the claims 1-11, where the springs are of material MP 35 or similar.
- 10 13. The prosthetic device according to claim 1, where the springs are attached to the base plate in conical holes, where the wider end of a conical hole projects towards to the spring.

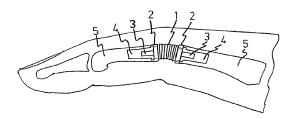


FIG. 1

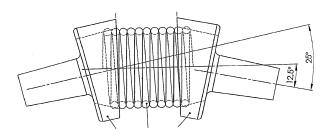


FIG. 2

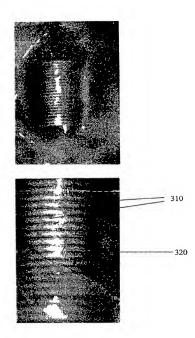
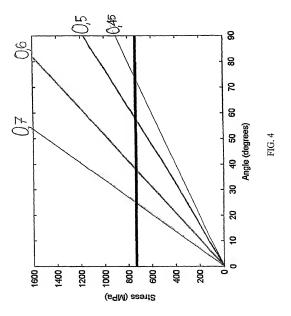
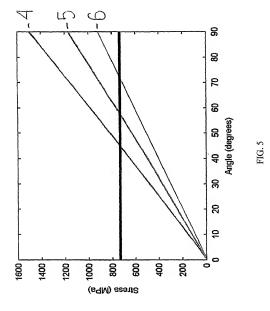
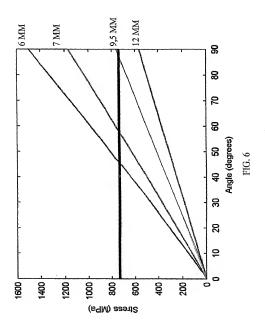
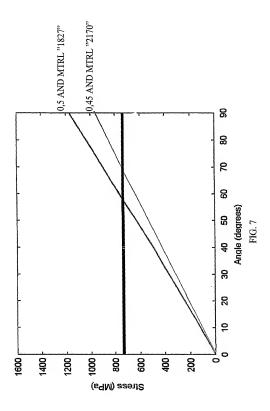


FIG. 3









INTERNATIONAL SEARCH REPORT

International application No.

			PCT/SE2007/	000312
A. CLAS	SIFICATION OF SUBJECT MATTER			
IPC:	see extra sheet			
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IPC:	A61F			
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Leif Brander/CM Telephone No. + 46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No. PCT/SE2007/000312

International patent classification (IPC) A61F 2/42 (2006.01) A61F 2/30 (2006.01)

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Information on patent family members 30/06/2007

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